DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 10, 2016

Bonutti Research, Inc.
Patrick G. Balsmann
Director, Regulatory/Clinical Affairs & QA
P.O. Box 1367
Effingham, Illinois 62401

Re: K161628
Trade/Device Name: JAS Pulse™ Ultrasonic Therapy
Regulation Number: 21 CFR 890.5300
Regulation Name: Ultrasonic Diathermy
Regulatory Class: Class II
Product Code: IMI
Dated: October 6, 2016
Received: October 11, 2016

Dear Patrick G. Balsmann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael J. Hoffmann -A

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161628

Device Name
JAS Pulse™ Ultrasonic Therapy

Indications for Use *(Describe)*

Application of therapeutic ultrasound for:

- Pain.
- Pain relief, muscle spasms, and joint contractures.
- Relief of pain, muscle spasms, and joint contractures that may be associated with:
  - o Adhesive capsulitis,
  - o Bursitis with slight calcification,
  - o Myositis,
  - o Soft tissue injuries, and
  - o Shortened tendons due to past injuries and scar tissues.

- Relief of pain, muscle spasms, and joint contractures resulting from:
  - o Capsular tightness, and
  - o Capsular scarring.

- Localized increase in blood flow.
- Increased range of motion of contracted joints using heat and stretch techniques.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Bonutti Research, Inc. – JAS Pulse™ Ultrasonic Therapy

November 9, 2016

ABBREVIATED 510(k) SUMMARY

The following information is submitted in accordance with the requirements of 21 CFR 807.92:

I. SUBMITTER:

Bonutti Research, Inc.,
P.O. Box 1367
Effingham, Illinois 62401

Contact Person:
Patrick Balsmann, MBA, MS, RAC
Director, Regulatory/Clinical Affairs & QA
Phone: (217) 342-3412, ext. 5106
Fax: (217) 342-1043

Date Prepared:
October 6, 2016

II. DEVICE:

Name of Device: JAS Pulse™ (JAS Pulse) Ultrasonic Therapy
Common Name: Therapeutic Ultrasound
Classification Name: Ultrasonic diathermy. For Use In Applying Therapeutic Deep Heat (21 CFR 890.5300)
Regulatory Class: II
Product Code: IMI

III. PREDICATE DEVICE(S)

Ito US-101L (K112520) – Primary Predicate
IBRAMED Sonopulse Compact 1 MHz (K131309)
Zimmer Soleo Sono (K121059)

IV. DEVICE DESCRIPTION

The JAS Pulse is a physical medicine ultrasonic diathermy device. The JAS Pulse device consists of a handheld transducer that generates high frequency sound waves. These sound waves penetrate tissue and are used to treat injured or painful areas of the body in order to alleviate symptoms and to stimulate blood flow. The handheld device is intended to be single patient use and is used with ultrasonic gels to facilitate coupling to the patient's skin surface and to enhance ultrasonic penetration.

Components of the JAS Pulse device include the handheld electrical control unit with user interface to select treatment power levels and time intervals. The controller drives the handheld treatment applicator to provide continuous and pulsed 1MHz therapeutic ultrasound. Ultrasonic gels applied to the user's area of pain facilitate ultrasonic coupling and penetration to facilitate the therapeutic ultrasound.

V. INDICATIONS FOR USE

Application of therapeutic ultrasound for:

- Pain.
- Pain relief, muscle spasms, and joint contractures.
- Relief of pain, muscle spasms, and joint contractures that may be associated with:
    - Adhesive capsulitis,
    - Bursitis with slight calcification,
    - Myositis,
    - Soft tissue injuries, and
    - Shortened tendons due to past injuries and scar tissues.

- Relief of pain, muscle spasms, and joint contractures resulting from:
    - Capsular tightness, and
    - Capsular scarring.

- Localized increase in blood flow.
- Increased range of motion of contracted joint using heat and stretch techniques.

Comparisons of the JAS Pulse device to its predicate devices indications demonstrate its substantial equivalence as follows:

Identical to Ito US-101L (K112520) – Primary Predicate:
(1) Relief of pain, muscle spasms, & joint contractures.

Identical to Zimmer Soleo Sono (K121059):

(1) Relief of pain, muscle spasms, & joint contractures.
(2) Relief of pain, muscle spasms, & joint contractures that may be associated with:
    - Adhesive capsulitis
    - Bursitis with slight calcification
    - Myositis
    - Soft tissue injuries
    - Shortened tendons due to past injuries & scare tissues.

Identical to Sonopulse Compact 1 MHz (K131309):

(1) Localized increase in blood flow.
(2) Increased range of motion of contracted joints.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICES

The table on the following pages demonstrates substantial equivalence of the JAS Pulse device to its predicate devices in terms of indications for use and technological characteristics:

The JAS Pulse device has two operating modes: High and Low. The High mode produces a continuous waveform at an acoustic intensity of 1.4 W/cm^2 (Output Power of 1.59 W). The predicate devices are also able to operate a continuous waveform at the same intensity. The Low mode produces a pulsed waveform with a duty cycle of 50% and pulse repetition of 10 ms (100Hz). The acoustic intensity produced during Low mode is 0.7W/cm^2 (Output Power of 0.79 W). The predicate devices can also operate with the same duty cycle, pulse repetition and acoustic intensity.

Regarding technological characteristics, the maximum effective intensity of the JAS Pulse is 1.4W/cm^2 (Continuous) and 0.7 W/cm^2 (Pulsed), while the Sonopulse is 3 W/cm^2, the US-101L is 2 W/cm^2 (Continuous) and 3 W/cm^2 (Pulsed), and the Soleo Sono is 1W/cm^2. The maximum output power of the JAS Pulse is 1.59 W (Continuous) and 0.79 W (Pulsed), while the Sonopulse 21 W, the US-101L is 11 W (Continuous) and 16.5 W (Pulsed), and the Soleo Sono is 1 W. The ERA of the JAS Pulse is 1.133 cm^2 compared to 1 cm^2 (Sonopulse), 5.5 cm^2 (US-101L), or 7 cm^2 (Soleo Sono). Differences between the JAS Pulse and the predicate devices were evaluated in performance and effectiveness testing and the JAS Pulse was found to be substantially equivalent to the predicate devices.

Device Feature/ Manufacturer	JAS Pulse Subject Device	Ito US-101L Primary Predicate	IBRAMED Sonopulse Compact 1MHz Predicate Device	Zimmer Soleo Sono Predicate Device	Comparison to Predicates
510(k)	Current (K161628)	K112520	K131309	K121059	Current to Predicates
Indications for Use	Application of therapeutic ultrasound for: • Pain. • Pain relief, muscle spasms, and joint contractures. • Relief of pain, muscle spasms, and joint contractures that may be associated with: o Adhesive capsulitis, o Bursitis with slight calcification, o Myositis, o Soft tissue injuries, and o Shortened tendons due to past injuries and scar tissues. • Relief of pain, muscle spasms, and joint contractures resulting from: o Capsular tightness, and o Capsular scarring. • Localized increase in blood flow. • Increased range of motion of contracted joints using heat and stretch techniques.	The US-101L, US-103S are indicated for use in applying therapeutic deep heat in body tissue for the treatment of selected medical conditions including for relief of pain, muscle spasms, & joint contractures.	Therapeutic ultrasound • Pain relief • Reduction of muscle spasms • Localized increase in blood flow • Increase range of motion of contracted joints using heat & stretch techniques.	Ultrasound Therapy Relief of pain, muscle spasms, & joint contractures Relief of pain, muscle spasms, & joint contractures that may be associated with: • Adhesive capsulitis • Bursitis with slight calcification • Myositis • Soft tissue injuries • Shortened tendons due to past injuries & scare tissues. Relief of pain, muscle spasms, & joint contractures resulting from: • Capsular tightness • Capsular scarring	Identical to Soleo Sono: (1) Relief of pain, muscle spasms, & joint contractures. (2) Relief of pain, muscle spasms, & joint contractures that may be associated with: • Adhesive capsulitis • Bursitis with slight calcification • Myositis • Soft tissue injuries • Shortened tendons due to past injuries & scare tissues. Identical to Sonopulse: (1) Localized increase in blood flow. (2) Increased range of motion of contracted joints.

Device Feature/ Manufacturer	JAS Pulse Subject Device	Ito US-101L Primary Predicate	IBRAMED Sonopulse Compact 1MHz Predicate Device	Zimmer Soleo Sono Predicate Device	Comparison to Predicates
510(k)	Current (K161628)	K112520	K131309	K121059	Current to Predicates
System Components	ABS plastic material with screw assembly construction The transducer is constructed of Ultem plastic with a molded silicone grip	Plastic enclosure with handheld transducer applicator.	Plastic enclosure with handheld transducer applicator.	PC-ABS plastic material with screw assembly construction	Identical in plastic construction to each predicate.
Console/generator Dimensions (L x W x H)	10.5cm x 6.7cm x 2.5cm	5.5cm x 5.9cm x 13.4cm	16.6cm x 27cm x 12.5cm	32.2cm x 23.4cm x 13cm	Different, but does not adversely affect safety and effectiveness of the subject device
Console/generator Weight (kg)	0.151 kg (with transducer)	0.200 kg (with transducer)	1.400 kg (with transducer)	2.100 kg	Different, but does not adversely affect safety and effectiveness of the subject device
Treatment head dimensions (L x W x H cm)	6.35cm x 2.54cm x 2.54cm	13.4 cm x 5.9 cm x 5.5 cm	20cm x 6.35cm x 6.35cm	23cm x 5cm x 5cm	Different, but does not adversely impact safety and effectiveness of the subject device
Treatment head weight (kg)	0.026kg	0.200 kg (with generator)	1.400 kg (with generator)	0.850kg	Different, but does not adversely impact safety and effectiveness of the subject device
Power Source	AC Line 100-240V 50/60 Hz	AC 100-240 V 50/60 Hz	AC Line 100-240V 50/60 Hz	AC 100-240 V 50/60 Hz	Identical power source specifications.

Device Feature/ Manufacturer	JAS Pulse Subject Device	Ito US-101L Primary Predicate	IBRAMED Sonopulse Compact 1MHz Predicate Device	Zimmer Soleo Sono Predicate Device	Comparison to Predicates
510(k)	Current (K161628)	K112520	K131309	K121059	Current to Predicates
Patient Leakage Current: Normal Condition	3uA Meets IEC 60601-1, section 8.7 LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS	Information not provided in the publically available 510(k)	Information not provided in the publically available 510(k)	< 1mA	Similar
Patient Leakage Current: Single Fault Condition	5uA Meets IEC 60601-1, section 8.7 LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS	Information not provided in the publically available 510(k)	Information not provided in the publically available 510(k)	<0.5mA	Similar.
Crystal material	PZT	PZT	PZT	PZT	Identical to each predicate.
Technology of ultrasound generation	Piezoelectric	Piezoelectric	Piezoelectric	Piezoelectric	Identical to each predicate in piezoelectric technology to generate ultrasound energy is industry standard.
Acoustic working frequency and accuracy	1.0 MHz ± 10%	1.0 MHz ± 10%	1.1 MHz ± 10%	0.8 MHz ± 10% 2.4 MHz ± 10%	Within range of ultrasound diathermy devices per CFR 890.5300 (a)
Treatment Waveform Modes	Pulsed & Continuous	Pulsed & Continuous	Pulsed & Continuous	Pulsed & Continuous	Identical to each predicate.

Device Feature/ Manufacturer	JAS Pulse Subject Device	Ito US-101L Primary Predicate	IBRAMED Sonopulse Compact 1MHz Predicate Device	Zimmer Soleo Sono Predicate Device	Comparison to Predicates
510(k)	Current (K161628)	K112520	K131309	K121059	Current to Predicates
Timer settings and accuracy	0 - 15 minutes ± 0.2 minutes	0 - 30 minutes ± 1 minute	0 - 30 minutes (accuracy not listed)	0 - 30 minutes (accuracy not listed)	Equivalent to each predicate. Treatment time is determined by size of treatment site. JAS Pulse allows for multiple sessions to treat larger areas as noted in JAS Pulse Instruction Manual.
Beam Type	Collimated	Collimated	Collimated	Collimated	Identical to each predicate.
Applicator Size	Diameter: 2.56 cm Area: 5.15 cm^2	Diameter:2.1cm Area: 3.5 cm^2	Diameter: 3cm Area: 7cm^2	Diameter: 1.3 cm Area: 1 cm^2	Different but does not adversely impact safety and effectiveness of the subject device.
Maximum value of the effective intensity and accuracy (not to exceed 3W/cm^2)	Continuous (High): 1.4 W/ cm^2 Pulsed (Low): 0.7 W/ cm^2 (all values ± 20%)	Continuous: 2 W/ cm^2 Pulsed: 3 W/ cm^2 (all values ± 20%)	Continuous: 3.0 W/ cm^2 Pulsed: 3.0 W/ cm^2 (all values ± 20%)	Continuous: 1W/cm^2 (800kHz) 1.1W/cm^2 (2.4MHz) Pulsed: 1W/cm^2 (800kHz) 1.1W/cm^2 (2.4MHz) (all values ± 20%)	Different but does not adversely impact safety and effectiveness of the subject device and complies with IEC60601-2-5

Device Feature/ Manufacturer	JAS Pulse Subject Device	Ito US-101L Primary Predicate	IBRAMED Sonopulse Compact 1MHz Predicate Device	Zimmer Soleo Sono Predicate Device	Comparison to Predicates
510(k)	Current (K161628)	K112520	K131309	K121059	Current to Predicates
Output Power	Continuous (High): 1.59W Pulsed (Low): 0.79W (all values ± 20%)	Continuous: 0 - 11 W Pulsed: 0 - 16.5 W (all values ± 20%)	Continuous: 7 cm^2 : 0.7 - 21 W Pulsed: 7 cm^2 : 0.7 - 21 W (all values ± 20%)	Continuous: 1cm^2: 0 - 1W (800kHz) 0 - 0.6W (2.4MHz) Pulsed: 1cm^2: 0 - 1W (800kHz) 0 - 0.6W (2.4MHz) (all values ± 20%)	Similar to Soleo Sono. Different from Sonopulse and US-101L but does not adversely impact the safety and effectiveness of the subject device and complies with IEC 60601-2-5
Maximum value of the temporal-maximum output power and accuracy (W)	Continuous (High): 1.59W Pulsed (Low): 0.79W (all values ± 20%)	Continuous: 11W Pulsed: 16.5W (all values ± 20%)	Continuous: 7 cm^2 : 21 W Pulsed: 7 cm^2 : 21 W (all values ± 20%)	Continuous: 1cm2: 1W Pulsed: 1cm2: 1W (all values ± 20%)	Different but does not adversely impact safety and effectiveness of the subject device and complies with IEC60601-2-5
Maximum value of temporal-maximum intensity and accuracy	Continuous (High): 1.4 W/ cm^2 Pulsed (Low): 0.7 W/ cm^2 (all values ± 20%)	Continuous: 2 W/ cm^2 Pulsed: 3 W/ cm^2 (all values ± 20%)	Continuous: 3.0 W/ cm^2 Pulsed: 3.0 W/ cm^2 (all values ± 20%)	Continuous: 1W/cm^2 (800kHz) 1.1W/cm^2 (2.4MHz) Pulsed: 1W/cm^2 (800kHz) 1.1W/cm^2 (2.4MHz) (all values ± 20%)	Different but does not adversely impact safety and effectiveness of the subject device and complies with IEC60601-2-5

Device Feature/ Manufacturer	JAS Pulse Subject Device	Ito US-101L Primary Predicate	IBRAMED Sonopulse Compact 1MHz Predicate Device	Zimmer Soleo Sono Predicate Device	Comparison to Predicates
510(k)	Current (K161628)	K112520	K131309	K121059	Current to Predicates
Pulse duration	Continuous (High): 10ms Pulsed (Low): 5ms	Continuous: 10ms Pulsed: .5ms, 1ms, 2ms, 3ms, 4ms, 5ms, 10ms depending on selected program	Continuous: 10ms (10ms pulse repetition selected), 6.3ms (6.3ms pulse repetition selected), 2.1ms (2.1ms pulsed repetition selected) Pulsed: 0.42 ms, 1.05 ms, 1.24 ms, 2 ms, 3.15 ms, 5ms depending on selected program	Continuous: 50ms (50ms pulse repetition selected, 20ms (20ms pulse repetition selected), 10ms (10ms pulse repetition selected) Pulsed: 1ms, 2ms, 3.3ms, 4ms, 5ms, 6.7ms, 10ms, 16.7ms, 20ms, 25ms, 50ms depending on selected program	Identical to settings 100Hz at 50% duty cycle, and 100%
Pulse repetition	Continuous (High): 10ms(100Hz) Pulsed (Low):10ms (100Hz)	Continuous: 10ms (100 Hz) Pulsed: 10ms (100 Hz)	Continuous: 10ms,6.3ms, 2.1ms (100Hz,10Hz,48 Hz) Pulsed: 10ms,6.3ms, 2.1ms (100Hz,10Hz,48 Hz) Depending on selected program.	Continuous: 50ms, 20ms, 10ms (20Hz,50Hz,100Hz) Pulsed: 50ms, 20ms, 10ms (20Hz,50Hz,100Hz) Depending on selected program.	Identical to US-101L,Soleo Sono 100 Hz setting, and Sonopulse 100 Hz setting.
Duty factor and accuracy	Continuous (High):100% Pulsed (Low): 50%	Continuous: 100% Pulsed: 5%, 10%, 20%, 30%, 40%, 50%	Continuous: 100% Pulsed: 20%, 50%	Continuous: 100% Pulsed: 50%, 30%, 20%, 10%	Identical to SoleoSono, Sonopulse, US-101L 100% and 50% duty cycle settings
Ratio of temporal maximum output power to the output power	Continuous (High): 1:1, Pulsed (Low): 2:1	Continuous: 1:1 Pulsed: 20:1, 10:1, 5:1, 3.3:1, 3:1, 2:1	Continuous: 1:1 Pulsed: 5:1, 2:1	Continuous: 1:1 Pulsed: 2:1, 3:1. 5:1, 10:1	Equivalent to predicate at equivalent settings.

Device Feature/ Manufacturer	JAS Pulse Subject Device	Ito US-101L Primary Predicate	IBRAMED Sonopulse Compact 1MHz Predicate Device	Zimmer Soleo Sono Predicate Device	Comparison to Predicates
510(k)	Current (K161628)	K112520	K131309	K121059	Current to Predicates
Maximum patient contact surface temperature of the treatment head under simulated or actual use conditions for all operating conditions (continually operated for maximum treatment time) (°C)	Transducer surface does not exceed 43 °C when measured under test conditions 201.11.1.3.101.1 as stated in IEC 60601-2-5.	Meets IEC 60601-2-5, section 201.11 Protection against excessive temperature and other HAZARDS.	Meets IEC 60601-2-5, section 201.11 Protection against excessive temperature and other HAZARDS.	Meets IEC 60601-2-5, section 201.11 Protection against excessive temperature and other HAZARDS.	Same
Beam Nonuniformity Ratio (BNR) and accuracy	2.5 ± 30%	3.5 ± 30%	7 cm^2: 3	4.3:1 or less	Different but does not adversely impact safety and effectiveness of the subject device and complies with IEC60601-2-5

Device Feature/ Manufacturer	JAS Pulse Subject Device	Ito US-101L Primary Predicate	IBRAMED Sonopulse Compact 1MHz Predicate Device	Zimmer Soleo Sono Predicate Device	Comparison to Predicates
510(k)	Current (K161628)	K112520	K131309	K121059	Current to Predicates
Effective radiating area (ERA) and accuracy (cm^2)	1.133 cm^2 ± 20%	5.5 cm^2 ± 20%	7 cm^2 (accuracy not listed)	1 cm^2 : 1,08 cm^2 (0,8 MHz) 0,54 cm^2 (2,4 MHz) (all values ± 20%)	Similar to Soleo Sono 1cm2 treatment applicator. Different from Sonopulse and US_101L but does not adversely impact safety and effectiveness of the subject device and complies with IEC60601-2-5
Electrical Safety Standards Compliance	IEC 60601-1 IEC 60601-2-5 IEC 60601-1-2	IEC 60601-1 IEC 60601-2-5 IEC 60601-1-2	IEC 60601-1 IEC 60601-2-5 IEC 60601-1-2	IEC 60601-1 IEC 60601-2-5 IEC 60601-1-2	Identical to each predicate for compliance.

VII. PERFORMANCE DATA

The following performance data were provided in support of substantial equivalence of JAS Pulse to its predicate devices:

Electrical Safety and Electromagnetic Compatibility (EMC)

JAS Pulse electrical safety & EMC testing to the following FDA recognized standards was conducted with the JAS Pulse demonstrating compliance:

- IEC 60601-1-2 Edition 3: 2007-03
- AAMI/ANSI ES 60601-1:2005/(R)2012 and A1:2012
- IEC 60601-1-6 Edition 3.0: 2010-01
- AAMI 62366
- IEC 60601-2-5: Edition 3.0 2009-07

VIII. CONCLUSIONS

The JAS Pulse™ (JAS Pulse) Ultrasonic Therapy device has the same indications for use as the predicate ultrasound diathermy devices in application of therapeutic ultrasound for pain relief. JAS Pulse devices were tested to current FDA recognized and international electrical safety, EMC, and ultrasonic physiotherapy equipment standards demonstrating compliance. Software verification and validation with risk analysis of the JAS Pulse device was further conducted to identify and mitigate associated risks.

In summary, the JAS Pulse device is substantially equivalent (SE) to existing predicate ultrasound devices determined SE by FDA and as listed in Section III of this Summary.